(New) The polypeptide of claim 41, in which the peptide units are randomly ordered in a series consisting of two to four kinds of peptide units selected from the group consisting of Φ, Γ, Δ and Ω.

REMARKS

Status of Claims

Claims 31, 34, 37-50 are pending.

Claims 45-50 have been withdrawn from consideration.

Claims 31, 34, and 37-44 were rejected.

By the way of this reply, claim 41 has been amended and claims 51 and 52 have been added.

Upon entering this amendment, claims 31, 34, 37-52 will be pending.

Summary of the Amendment

The specification has been amended to include a reference of the claim of priority to U.S. Application No. 07/945,280, filed September 15, 1992. Applicants request a corrected filing receipt that reflects this claim of priority.

Claim 41 has been amended to clarify the composition of the polypeptide. This amendment clarifies that the polypeptide is composed of a series of 1 - 1000 peptide units. The peptide units consist of four kinds of peptide units, Φ, Γ, Δ and Ω.

Claims 51 and 52 have been added to clarify that the polypeptide may consist of peptide units that are homogeneous for one kind of peptide unit, or randomly ordered in a

series consisting of two to four kinds of peptide units. Support for these claims is found in the specification on page 8, line 28 - page 9, line 4. No new matter has been added.

Attached hereto is a marked-up version of the changes made to the specification and the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Supplemental Information Disclosure Statement

The IDS previously filed in the present application contained errors in the identification of the application. Consequently, it is not clear which references have in fact been considered. Therefore, a Supplemental Information Disclosure Statement is filed herewith listing all of the references currently known to be relevant to the instant application. The Examiner may have already considered several of these references.

Rejections under 35 U.S.C. § 112, First Paragraph

A. Claims 31 and 42 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains to use the invention. Applicants traverse this rejection. The specification enables one of skill in the art to use of the pharmaceutical composition of claims 31 and 42 without undue experimentation.

The enablement requirement of 35 U.S.C. § 112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8

U.S.P.Q.2d 1400 (Fed. Cir. 1988). Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

The specification discloses several uses for the pharmaceutical composition of claims 31 and 42, including the use for the purposes of immunization to produce monoclonal antibodies specific to the polypeptide (specification, page 13, lines 17-19, and other places). Methods to make monoclonal antibodies were well known to those in the art, and applicable methods are further disclosed (specification page 12, lines 2-13). The Office Action has not presented any evidence or reasoning why the pharmaceutical compositions of the invention could not be used by one of skill in the art to make monoclonal antibodies.

B. Claims 31, 34, 37-44 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor was in possession of the invention at the time the application was filed. Applicants traverse the rejection of claim 37. Claim 41 has been amended to clarify the composition of the claimed polypeptide. The subject matter of claim 37 and amended claim 41 and dependent claims 31, 34, 38-40, and 42-44 are described in the specification and recite no new matter.

An applicant's specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111,

1117 (Fed. Cir. 1991). The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 262, 191 USPQ 90, 98 (CCPA 1976).

The Office Action asserts that claim 37 recites new matter because it encompasses peptides that are less than 15 amino acids in length (Office Action, page 4, line 7). This is incorrect. Claim 37 recites "Φ is 25 amino acids or less and has the formula: $(\alpha$ETFTETWNRFITHTE$\beta)_n$." Therefore, while the peptide may be less than 25 amino acids in length, it must also contain the 15 amino acid sequence ETFTETWNRFITHTE, so it cannot be less than 15 amino acids in length. The written description for the peptide containing the sequence ETFTETWNRFITHTE and 0-10 additional amino acids is found in the specification on page 8, lines 22-24, and does not constitute new matter.

The Office Action asserts that claim 41 recites new matter. Claim 41 has been amended to clarify the composition of the polypeptide. The disclosure of the equation of claim 41 is found in the description of the invention on pages 8 and 9 of the specification, and other places.

> The polypeptides of the invention can also be utilized as repeating units ranging from 1 to about 1000 units in length. These units can be homogeneous, for example, where all of the units are repeats of the same polypeptide or can be mixtures of the polypeptides of the invention.

(Specification page 8, line 28 - page 9, line 4). The symbols Φ, Γ, Δ and Ω refer to the polypeptides of the invention used as peptide units, as defined on page 8, lines 2-5, and lines 20-24. The polypeptide of claim 41 can be homogenous for one kind of the peptide unit, or a mixture of the several kinds of peptide units. Φ, Γ, Δ and Ω will be at least 15 amino acids in length because they contain the recited formula (explained above, and discussion

incorporated by reference herein). As there is no recitation of a particular repeated multimer in the claims, there is no requirement for the disclosure of a specific multimer in the specification.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

Rejections under 35 U.S.C. § 102(b)

A. Claims 31, 34, 37-44 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Smith et al. (WO 94/06470). If one discloses his or her own work more than 1 year before the filing of the patent application, that person is barred from obtaining a patent. *In re Katz*, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982). A national application is entitled to the right of priority based on a prior filed international application which designated at least one country other than the Untied States. 35 U.S.C. § 365(a). Applicants traverse this rejection. Smith et al. was published after the effective filing date of the present invention and is not prior art under 35 U.S.C. § 102(b).

The present application is the national phase of PCT/US93/08699, filed September 15, 1993. Applicants refer to the Declaration submitted September 22, 2000, which is signed by all four inventors and claims priority to PCT/US93/08699, filed September 15, 1993 and to US Application No. 07/945,280, filed September 15, 1992. Claims 31, 34, 37-44 recite no new matter and are entitled to the priority date of PCT/US93/08699. No new material was added to the specification upon entering the national phase, and the present specification is identical to PCT/US93/08699. As the cited reference,

Smith et al. (WO 94/06470), is the publication of PCT/US93/08699, when the Office Action asserts that claims 31, 34 and 37-44 are anticipated by Smith et al., it concedes that claims 31, 34 and 37-44 are described in PCT/US93/08699, and are therefore entitled to the effective filing date of PCT/US93/08699. In addition, the subject matter of claims 31, 34, 37-44 is disclosed in the present specification (discussed above, and discussion incorporated by reference herein), and therefore at the same places in PCT/US93/08699. Therefore, Smith et al. (WO 94/06470) cannot be §102(b) prior art because it was published after the effective filing date of the invention.

B. Claims 37, 40, 41 and 44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Pothen et al. While no year of publication is given for Pothen et al. in the Office Action, Applicants infer it is the 1993 reference (Int. J. Cancer 53, 199-204) as it contains Table 1 with amino acid sequences, while Pothen et al., 1991 (Int. J. Cancer 49, 656-660) does not. Applicants traverse this rejection. Pothen et al. (1993) is not prior art under 35 U.S.C. § 102(b).

The present application is the national phase of PCT/US93/08699, September 15, 1993, and claims priority to US Application No. 07/945,280, filed September 15, 1992 (discussed above, and incorporated herein in its entirety). Pothen et al., 1993 (Int. J. Cancer 53, 199-204) appeared in the January 21, 1993 issue of the International Journal of Cancer Research. This publication date is less than one year before the filing date of PCT/US93/08699, September 15, 1993, and after the filing date of US Application No. 07/945,280, and therefore is not prior art under 35 U.S.C. § 102(b). The Office Action

concedes that claims 37, 40, 41 and 44 are fully described in PCT/US93/08699 (discussed above, and discussion incorporated by reference herein). Additionally, the peptides described in Pothen et al. (1993) are disclosed in the priority application 07/945,280 on page 7, lines 3-4. Therefore, Pothen et al. does not describe the peptides of claims 37, 40, 41 and 44 more than one year before the effective filing date of the present application and is not prior art under § 102(b).

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 102(b) be withdrawn. Conclusion

For the foregoing reasons, Applicants submit that the present claims meet all the requirements for patentability. The Examiner is respectfully requested to allow all the present claims. If the Examiner is of a contrary view, it is requested that he contact the undersigned at (215)557-5948.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The following title and paragraph has been added to the specification before the "Field of the Invention" on page 1.

Cross-Reference to Related Applications

This Application is the national phase of PCT/US93/08699, filed September 15, 1993, which claims priority to U.S. Application No. 07/945,280, filed September 15, 1992, abandoned January 31, 1994.

In the claims:

Claim 41 has been amended as follows:

41. **(Amended)** A polypeptide consisting of ~~an amino acid sequence~~ a series of one to 1000 peptide units selected from the group consisting of peptide units Φ, Γ, Δ and Ω, ~~having the formula:~~

~~$\{(\Phi)_n(\Gamma)_o(\Delta)_p(\Omega)_q)\}_r$~~

wherein:

~~n is 0-1000,~~

~~o is 0-1000,~~

~~p is 0-1000,~~

~~q is 0-1000,~~

~~n + o + p + q = 0-1000,~~

~~(n + o + p + q) x r = 1-1000,~~

Φ is 25 amino acids or less and has the formula (αETFTETWNRFITHTEβ),

Γ is 25 amino acids or less and has the formula (αGMLEASEGLDGWIHQβ),

Δ is 25 amino acids or less and has the formula (αHQQGGWSTLIEDNIPβ),

Ω is 25 amino acids or less and has the formula (αKQKHPKKVKQAFNPLβ),

α and β are each independently from 0 to 5 naturally occurring amino acids, and

the polypeptide is capable of binding antibody in a specimen from an individual with Epstein-Barr virus (EBV)-associated disease.

Claims 51 and 52 have been added.

51. **(New)** The polypeptide of claim 41, which is homogeneous for one kind of peptide unit selected from the group consisting of Φ, Γ, Δ and Ω.

52. **(New)** The polypeptide of claim 41, in which the peptide units are randomly ordered in a series consisting of two to four kinds of peptide units selected from the group consisting of Φ, Γ, Δ and Ω.